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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,895	03/31/2004	Tomoko Takeshita	HIRA.0147	5008

7590 08/28/2006

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EXAMINER	
NOBLE, MARCIA STEPHENS	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/812,895	TAKESHITA ET AL.	
	Examiner	Art Unit	
	Marcia S. Noble	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 10-15 are pending. Claim 1-9 were previously cancelled. Claims 10, 11, and 13-15 are amended by Applicant's Response, filed 6/5/2006. Claims 10-15 are under consideration.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The preliminary amendment received on 6/5/2006 specifies the entry of the priority claim to 09/666,615 in the first line of the specification immediately following the title. This rectifies the previous amendment to the specification, filed on 3/31/04, which improperly directed the priority claim to the first paragraph under the Background of Invention.

In the Non-Final Rejection, mailed 2/3/2006, acknowledgment was made of applicant's claim for foreign priority based on an application filed in Japan on 8/25/2000. It was noted, however, that applicant has not filed a certified copy of the Japanese application as required by 35 U.S.C. 119(b). In Applicant's Response, filed 6/5/2006, Applicant contends that a copy was received in the patent application such that there is no need to submit another copy in the current file. However, a certified copy of the priority document is not present in the instant application. Therefore, priority can not be given to the date of the priority document.

Oath/Declaration

3. The oath or declaration was objected to as being defective and a new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date was requested. (See MPEP §§ 602.01 and 602.02.)

> The oath or declaration was considered defective because: it referred to the specification of 09/666,530 and not the specification of parent application 09/666,615.

Applicant traverses this rejection stating that a new copy of the oath or declaration is not required, because MPEP specifies that the Applicant can use the oath or declaration from the parent application in a continuation or divisional application. This argument is found persuasive, however, it is noted that applicant does not receive priority to 09/666,530 as claimed in the declaration because it is not listed in the first paragraph of the specification. The objection is withdrawn.

Claim Objections

4. Claim 10 was objected to because of the following informalities. The claims were amended and therefore this rejection is withdrawn.

Claims 11-12 depend from claim 10 and therefore the rejection is withdrawn for the dependent claims as well.

Claims 13 was objected to as indefinite in its recitation of "one kind of mRNA". Applicant amended the claim to recite an mRNA which encodes a protein, therefore

clarifying the claim. Therefore, there objection is withdrawn. The instant objection to the dependent claims 14 and 15 is also withdrawn.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 10-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Claims 10 and 13 recite "an identical depth". The specification does not provide literal support for an "identical depth". The specification provides some figurative support for injection at a controlled depth between the range of 0.02-0.1 mm (p. 9, lines 25-27). However, this would not be considered "an identical depth" as claimed because the depth can varying anywhere between 0.02 and 0.1 mm. Claims 11, 12, 14, and 15 are dependent upon 10 and 13 and therefore also recite the new matter.

Claim 13 also recites "initiating a biological interaction with said sample". However, the specification does not provide literal support for "a biological interaction". The specification provides some figurative support for a method of injecting the oocytes

using the disclosed apparatus and comparing the result of reactions of oocytes with different ligands (p.15, lines 7-10). However, this does not teach an specific biological interactions with a sample as claimed.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 10-15 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

The specification states that the instant invention can inject into the cytoplasm in a range between 0.02 and 0.1 mm or into the nucleus at a 0.5-0.2 mm from the oocyte surface (p. 9 lines 25-29). The specification also discloses that the injection depth will be different depending on the samples to be injected (p. 9, lines 20-21) and also states that the form of the oocyte maybe deformed at the injection and therefore the sample is injected at a shallower position than the predetermined depth (sentence bridging p 9 an d10). Therefore, the specification suggest to levels of variation in the injection depth for which can not be controlled. The first is the range of the predetermined injection depth of 0.02 to 0.1 mm suggest that the invention can not provide and exact or "identical depth", as claimed. The second is the natural variability in the embryo shaped which can result in additional variability outside of the variable of the predetermined injection depth. Given that there is intrinsic and extrinsic variability to the injection depth by the apparition and method claimed, an artisan would not know how to make a plurality of

oocytes with the claimed "identical depth" of injection nor would they know how the use a method that required an "identical depth" of the injection.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure" (emphasis added).

Claim Rejections - 35 USC § 112, 2nd paragraph, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 10-15 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 was indefinite as written because it did not set forth the relationship between the injected mRNA molecule and the membrane potential. The amendment to the claims now provide a relationship between the injected mRNA molecule and the membrane potential. Therefore, the instant rejection is withdrawn. Claims 14-15 depend from claim 13. Therefore, the instant rejection is withdrawn from the dependent claims as well.

The term "substantially" in claims 10 and 13 was a relative term, which renders the claim indefinite. Claims were amended to no longer recite, "substantially"; therefore the rejection is rendered moot.

Amended claim 10 recites "mRNA which is respectively injection". The metes and bounds of "respectively" are unclear because "respectively" is uses when list of objects are specifically defined in a sequence. For example, A, B, and C, are equal to 1, 2, and 3, respectively. The instant claims only refer to one object, "a **plurality** of oocytes", therefore is not clear which and what sequence of oocytes are being injected. Claims 11 and 12 are dependent on claim 10, and therefore, they are rendered indefinite as well.

Amended claim 13 is also deemed indefinite because the relationship between the claimed solution and sample is not clear, in part due to a lack of antecedent basis. Claim 13 recites the limitation "a sample" in line 1, "a solution" in line 8, and "the

solution containing said sample" in lines 11-12. The method is screening "a sample", however the adding step of line 8 adds a solution. This solution has no link to the said sample of the claims. As recited it may or may not have the sample of interest. The following measuring step recites "the solution containing said sample". This lack insufficient antecedent basis for this limitation in the claim because it is unclear if the previous solution contains sample or not. Claims 14 and 15 are dependent on claim 13, therefore they are also rendered indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 10-15 stand rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al (5,688,938).

Applicant traverses this rejection on the grounds that Brown et al does not teach mRNA injected at an identical depth from the surface of the oocyte of each oocyte and that the instant product, the plurality of oocyte, has unexpected properties of "to provide expression efficiency" that are unknown and non-inherent when produced by the method disclosed by the specification.

This argument is not found persuasive for several reasons. First, as previously described in the Non-Final Action (sentence bridging p 4 to 5 and sentence following on p 5), the specification of Brown et al does define the injection depth as 0.02-0.1 from the cell surface via an injection into the vegetal pole. This provides no more or less of an "identical injection depth" than that of the instant claims (see claim 12 and 15). Second, claims 10-12 are drawn to a product that required mRNA injected into is cytoplasm. As long as the product has the same components it can be produced by any means. Brown discloses oocytes with an mRNA in its cytoplasm that has injected into its cytoplasm, therefore meeting the limitations of the claims. Third, the argument of unexpected properties that are unknown and non-inherent suggests the intent of a product by process claim however the claims do not indicate the specific automated method by which the intended product was produced as described by the specification. Therefore, it does not distinguish itself from other products in the art, such as Brown et al. Therefore the rejection stands.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 10-12 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-16, 18, 21, 24 and 26-27 of U.S. Patent No. 6,593,129. However, upon further consideration of the method of claim 13-15, the instant claims of '129 do not encompass the methods of screening, therefore the rejection of 13-15 is withdrawn.

Applicant traverses this rejection on the grounds that the amended claims recite an identical depth of injection which is not encompassed by the claims of '129. This argument is not found persuasive because of claims 14 of '129 recites "setting the depth of said injection need for said tray or said amphibian oocytes as a first depth; injecting the sample into the first oocyte using said injection needle at said first depth; automatically moving said tray relative to said injection needle; and subsequently injecting the sample into a second oocyte of said amphibian oocytes by inserting said injection needle to said first depth". Since both oocytes are receiving the injection at "said first depth", they are receiving injection at identical depths. Furthermore, claim 16 specifies the sample as a gene which can be an mRNA. Therefore, the method of '129 would result in the claimed product. Therefore the instant rejection of 10-12 stands.

9. Claims 10-12 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,803,207.

Applicant traverses this rejection on the grounds that the amended claims recite an identical depth of injection which is not encompassed by the claims of '207. These arguments are not found persuasive because, as described above, a product as long as is have the same components can be made by any means.

In considering a product, such as the plurality of oocytes into which mRNA is respectively injected of the instant invention, its patentability **does not** depend upon the manner by which the product was produced (See MPEP 2113.). Therefore, the method claims of '207 would result in the plurality of oocytes into which mRNA is respectively injected. Therefore, the rejection stands.

10. Claims 10-12, provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/774,613, have gone abandoned. Therefore, the rejection is moot.

11. Claims 10-15 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-16 of copending Application No. 10/876,551.

Applicant traverses this rejection on the grounds that the amended claims recite an identical depth of injection which is not encompassed by the claims of '551. As

described above, claims 10-12 of the instant application are a product by process at best that result in oocytes that have injected mRNA. The copending application claims 12-16 encompass these limitations, therefore the rejection of claims 10-12 stand. Claims 13 –15 of the instant application are drawn to a screening method that utilizes oocytes injected with mRNA. Claims 12-16 of instant claims encompasses these limitations. Eventhough, the methods of the copending application does not state an identical depth of injection. The end result of the methods are identical and the identical depth of the injection does not seem to add any characteristic to the invention that can be done accomplished by the copending screening method. Therefore, the rejection stands.

132 Declaration

12. The Declaration under 37 CFR 1.132 filed 6/5/2006 is insufficient to overcome the rejection of any claims because: the data provided does not suggest that the injection depth has a significant impact on electric current change (see fig 2). Applicant provided data in figure 1 describing a gene expression rate when DNA is injected into oocytes at a depth 0.2 mm. Since only one depth is reported, it is unclear how this compares to gene expression rates at other depths. Also, it is also unclear how this will translate to increased gene expression when an mRNA is injected at the disclosed optimum range of 0.02-0.1mm. Figure 2 provides data to show changes in electrical current change when the sample is injected at the same depth or a random depth. No apparent significant differences in electrical current change occur depending on

injection depth, therefore suggestive that the depth is not a significant factor. Finally, as previously discussed, the claims encompass "an identical depth" of injection, however the specification and this Affidavit disclose an optimal range, which does not encompass "an identical depth".

13. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. ·Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcia S. Noble